REMARKS

Prior to the present amendment, claims 1-39 were pending. By the present amendment, claims 6 and 39 have been cancelled and claim 40 has been added. Therefore, claims 1-5 and 7-38 and 40 are pending. Applicant reserves the right to prosecute the subject matter of claim 6 in an application that claims priority to the present application.

Claim 1 has been amended to remove a limitation. Claim 38 has been amended to depend from claim 1.

INFORMATION DISCLOSURE STATEMENT

Enclosed with this Response is another copy of Rezai et al., "Deep Brain Stimulation for Chronic Pain," in *Surgical Management of Pain*, Chapt. 44, pp. 565-576 (2002) (Appendix A), which was cited in the IDS filed on 23 July 2004. Applicant respectfully requests that the Form PTO-1449 included with the previously filed IDS be marked to confirm the Examiner's consideration of this reference.

REJECTIONS UNDER § 112

Claim 39 was rejected as allegedly being non-compliant with the definiteness requirement of § 112, second paragraph. Without conceding to the propriety of this rejection, claim 39 is canceled in order to expedite prosecution of this application. As such, this rejection is now rendered moot.

REJECTIONS UNDER § 101

Claim 39 was rejected under § 101 as allegedly being an improper process claim. Without conceding to the propriety of this rejection, claim 39 is canceled in order to expedite prosecution of this application. As such, this rejection is now rendered moot.

REJECTIONS UNDER § 103

A. King (Claims 1-36)

Claims 1-36 were rejected under § 103(a) as allegedly being rendered obvious by U.S. Patent No. 5,713,922 (King). Applicant respectfully requests reconsideration of this rejection at

least because King does not provide any motivation for modulating the particular sites recited by independent claims 1 and 19.

Conventional targets for brain stimulation in the treatment of pain include targets in the thalamus and King simply echoes what is already known in the art and which is pointed out by Applicant in the background section of this application. Specifically, King states that: "DBS is done today to excite particular neural tissue elements of the thalamus, globus pallidus and other nuclear groups for the relief of chronic pain or to control movements." (Col. 4, lines 33-35). Regarding the thalamus, it was known prior to the presently filed application that certain target sites in the thalamus were targeted for chronic pain. However, none of these previously known sites are recited by claim 19 (which is directed to deep brain sites).

Specifically, the book chapter "Deep Brain Stimulation for Chronic Pain" (attached as Appendix A) establishes that the ventroposterolateral (VPL) nucleus, ventroposteromedial (VPM) (also known as the ventralis caudalis (VC)/ventralis posterior (VP)) were previously targeted in an attempt to treat chronic pain (See page 566, first and second full paragraphs). Claim 1, in contrast, is not directed to such lateral thalamic nuclei but instead is directed to medial, intralaminar and anterior nuclei of the thalamus. There is no reason to believe that just because the lateral thalamic nuclei were targeted in the past that the medial, intralaminar and anterior nuclei should also be targeted now. This is particularly true given that the distinct nuclei in the thalamus project to and receive projections from different regions of the brain. Specifically, the VPL and VPL, project to the sensory motor cortex. In contrast, the dorsomedial nuclei and intralaminar nuclei (which are thalamic nuclei recited in claim 1) project to the frontal regions of the cortex and the anterior nuclei (which is also recited in claim 1) project to the parietal region of the cortex. Furthermore, the target sites identified in the art and the target sites currently claimed also have different ascending input. Therefore, if anything, there is reason to believe that stimulating different nuclei in the thalamus will have different effects.

Accordingly, by mentioning the "thalamus" which includes several distinct nuclear groups, King does not point to the specific nuclei recited by claim 19[1] and there is no reason given by the Examiner why one skilled in the art would target completely different nuclei than those previously targeted.

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[1] It should be noted that claim 1 is not being addressed in this rejection as the target sites in claim 1 are cortical target sites and King is absolutely silent as to cortical target sites.

Regarding claim 1, there is not even the slightest hint in King of stimulating cortical sites, which are the sites to which claim 1 is directed. For at least these reasons, Applicant submits that independent claims 1 and 19 are not rendered obvious by King.

B. King in View of Brown (Claims 1-36)

Claims 1-36 stand rejected under § 103(a) as allegedly being rendered obvious by King in view of J.A. Brown, *Neurosurg. Focus*, vol. 11(3), article 5 (Sept. 2001) ("Brown"). Applicant respectfully requests reconsideration of this rejection at least because Brown does not describe treating chronic pain in many instances and in other instances provide no motivation for modulating the particular sites recited by independent claims 1 and 19.

In one regard, Brown refers to an experimental study that was performed in rats.[2] While the rats were being subjected to electrical stimulation in the medial prefrontal cortex, their response to acute pain (inflicted by a hot-plate) was determined using tail-flick techniques. According to Brown, the study authors concluded that stimulation of the prefrontal cortex can provide pain relief. On this basis, the Office Action suggests that it would have been obvious to modify King to include not only the pre-frontal cortex, but also other areas of the cerebral cortex as targets for the treatment of acute pain. Applicant respectfully disagrees that Brown provides a sufficient reason to modify King in the manner suggested by the Office Action.

The rat experiments described in *Brown* studied acute pain, whereas claims 1 and 19 are directed to treating chronic pain. In clinical neuroscience, it is well understood that acute pain and chronic pain are different entities. (See attached article entitled: "The Difference between Acute and Chronic Pain") (attached as Appendix B). Acute pain is a normal protective response to injury, serves a useful biologic purpose, and is self-limited. In contrast, chronic pain continues beyond the normal time of healing and serves no known biologic purpose. This difference between acute and chronic pain is reflected in the treatment modalities that are employed. Because the treatment of acute pain is aimed at interrupting the nociceptive signals, acute pain is commonly treated with pain-killer medications, such as anti-inflammatory medications. In contrast, chronic pain is often treated with medications that are not typically associated with pain physiology, such as antidepressants or anticonvulsants. Moreover, chronic

[2] *Brown*, pg. 2, col. 1, first full paragraph.

pain is considered to be a far more complex condition than acute pain, requiring a multidisciplinary approach using a combination of treatment modalities.

Because chronic pain and acute pain are fundamentally different clinical entities, there could be no reasonable expectation that modifying *King* according to a study of acute pain in rats would be successful in treating chronic pain in patients.

Furthermore, regarding Brown's mention of the thalamus, Brown describes previous studies (as described above with respect to King) that have focused on regions of the thalamus other than the regions claimed in claim 19. Many of these studies are described in more detail in the article attached in Appendix A. Again, these studies targeted the lateral thalamus as opposed to the medial, anterior and intralaminar nuclei, to which claim 19 is directed.

Regarding claim 1, Applicant has amended claim 1 and assert that none of the target sites described by Brown are recited in claim 1. Regarding the post-central gyrus noted by the Examiner, claim 1 has been amended to delete the primary somatosensory cortex. Regarding the pre-central gyrus noted by the Examiner, this is also known as the primary motor cortex, which is not recited in claim 1. In fact, as described in the article attached in Appendix A and as described in the background section of the present application, the precentral gyrus was a site previously considered for evaluation in treating chronic pain and is not a site recited in claim 1.

Therefore, Brown simply summarizes prior studies that are directed to target sites that have actually been recognized by the Applicant in the present application in the background section of the application. Brown does not describe the sites that are recited in claims 1 and 19 (and all claims that depend therefrom). For at least these reasons, Applicant respectfully submits that independent claims 1 and 19, and all claims that depend therefrom are not rendered obvious by Brown in view of King.

C. Schiff (Claims 1-36)

Claims 1-36 stand rejected under § 103(a) as allegedly being rendered obvious by U.S. Patent No. 5,938,688 (Schiff). Applicant respectfully requests reconsideration of this rejection.

Schiff describes a method for treating impaired cognitive function by stimulation of the intralaminar nuclei.[3] Schiff is simply directed to an entirely different patient population. For at

[3] *Schiff*, col. 2, lns. 15-17.

least these reasons, Applicant respectfully submits that independent claims 1 and 19 (and all claims that depend therefrom) are not rendered obvious by Schiff.

D. King or Schiff in View of *Budai* (Claim 37)

Claim 37 stands rejected under § 103(a) as allegedly being rendered obvious by *King* or *Schiff* in view of Budai et al., *J. Neurophysiology*, vol. 79(2), pp. 677-687 (1998). Applicant respectfully requests reconsideration of this rejection.

Claim 37 recites a method of affecting chronic pain by implanting a stimulator in communication with a pain circuitry target site and providing a signal to stimulate the release of an endogenous opioid to affect chronic pain. The Examiner recognizes that none of the references describe this latter limitation but states that "[h]owever, Budai discloses that the inhibition of nociceptive neurons is mediated in part through the local release of an endogenous opioid acting at the μ opioid receptor." However, this statement does not provide any indication that providing a stimulation signal in a pain circuitry target site will result in the synthesis or release of an endogenous opioid. For at least this reason, Applicant submits that the combination of King or Schiff and Budai does not describe an express limitation of the claims.

E. King or Schiff in View of Rise (Claim 38)

Claim 38 stands rejected under § 103(a) as allegedly being rendered obvious by *King* or *Schiff* in view of U.S. Patent No. 6,109,269 (Rise et al.). Applicant respectfully requests reconsideration of this rejection.

Without conceding that the suggested combination of *King* or *Schiff* with *Rise* is proper, Applicant respectfully submits that this combination cannot meet the invention of claim 38, which now depends from claim 1 for at least the reasons mentioned above with respect to King and Schiff. Further, Rise does not make up for the deficiencies of King and Schiff. For at least these reasons, Applicant respectfully submits that claim 38 is non-obvious over King or Schiff in view of Rise. Accordingly, favorable consideration and withdrawal of the rejection is respectfully requested.

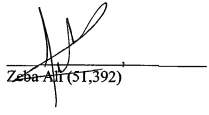
For the same reasons as stated above, Applicant also states that new claim 39 is also non-obvious over King or Schiff in view of Rise.

CONCLUSION

Applicant respectfully submits that the present application is in condition for allowance. The Examiner is invited to contact Applicant's representative to discuss any issue that would expedite allowance of this application.

The Commissioner is authorized to charge all required fees, fees under § 1.17, or all required extension of time fees, or to credit any overpayment to Deposit Account No. 11-0600 (Kenyon & Kenyon LLP).

Respectfully submitted,



Date: 10-19-07

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